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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,613	05/07/2002	Per Marin	ET 544 763 265 US	7969

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New York, NY 10112-4498

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,613	MARIN ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-21 and 24* is/are allowed.

6)☒ Claim(s) *22,23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 13-26 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed April 19, 2004 has been received and entered into the application. Accordingly, claims 13, 14, 18, 19 and 21 have been amended and claims 22-26 have been added.

In view thereof, the objection to the claims and all rejections set forth in the previous Office action dated October 23, 2003 are withdrawn.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23, 25 and 26 rejected are under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Written Description

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Claims 22, 23, 25 and 26 are directed to daily dosage ranges for cortisol antagonists, i.e., 200-800 mg (claims 22 and 25) and 300-600 mg (claims 23 and 26).

In the Amendment filed April 19, 2004, applicants have referred to the last paragraph of page 11 through the first paragraph of page 12 in support thereof. This section of specification reads:

"Suitable doses will vary from patient to patient and can be determined by the physician in accordance with the weight, age and sex of the patient and the severity of the condition and also the particular antagonist selected. A typical total daily dose will be in the region of 50 or 100-1200 mg of a cortisol antagonist which may be administered as a single dose or in several smaller doses during the day. Typical single doses will be in the region of 100-800 mg. Administration may advantageously be at around 10.00 p.m. in order to reduce cortisol activity during the night when natural cortisol levels are at their highest. Ketoconazole is preferably administered as a daily dose of 200-1000 mg, e.g. 300-600 mg.".

The present specification, as is clear from above, does not describe the presently claimed daily dosage ranges for the cortisol antagonists using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention concept. Nothing in the present specification would lead one to select 200-800 mg for the daily dosage range for cortisol antagonists of claims 22 and 25 and 300-600 mg for the cortisol antagonists of claims 23 and 26. Respecting the latter daily dosage range, such a range is specific to Ketoconazole (see last sentence in the quoted portion of the specification above), claims 23 and 26, however, are not directed to only ketoconazole.

Accordingly, claims 22, 23, 25 and 26 are deemed properly rejected.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Kohn et al. (U.S. Patent No. 5,565,478, newly cited by the Examiner).

Kohn et al. teach a composition that comprises ketoconazole and an additional drug (see claims 1 and 4 at col. 16 – col. 17).

The recitations in the present claim which related to how the composition is administered or how the composition is to be used does not impart patentable moment to the claimed composition because such recitations do not provide for any physical or otherwise material limitation not present in the prior art composition.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beale (U.S. Patent No. 6,756,469, already of record), in view of Walser (U.S. Patent No. 5,175,144, newly cited by the Examiner).

Beale teaches a composition that may comprise a cortisol blocker, i.e., a cortisol antagonist, and pyruvate, i.e., an additional drug (see e.g., the abstract).

The recitations in the present claim which related to how the composition is administered or how the composition is to be used does not impart patentable moment to the claimed

composition because such recitations do not provide for any physical or otherwise material limitation not present in the prior art composition.

The difference between the above and applicants' claimed subject matter lies in that Beale fails to teach ketoconazole as the cortisol blocker.

However, to the skilled artisan, the claimed subject matter would have been obvious because Walser teaches ketoconazole to be a cortisol blocker (col. 3, lines 36-43). The skilled artisan would have been motivated to employ ketoconazole in the composition of Beale because Beale teaches cortisol blockers may be employed while Walser teaches that ketoconazole meets that definition.

Allowable Subject Matter

Claims 13-17, 19-21 and 24 are deemed in condition for allowance because the prior art fails to suggest the presently claimed methods for the treatment of heart failure or the symptoms thereof wherein a cortisol antagonist is administered and wherein the cortisol antagonist is not clonidine.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0600.

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 13, 2004